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OBSERVATIONAL STUDIES TO CHARACTERIZE THE DETERMINANTS OF EXPOSURE TO CHEMICALS IN THE ENVIRONMENT FOR EARLY-LIFESTAGE AGE GROUPS

General Information

Announcement Type:	Initial Announcement
Funding Instrument Type:	CA
Funding Opportunity Number:	EPA-ORD-08-27294
Posted Date:	May 29, 2008
Due Date for Applications:	To be considered timely, printed applications must be received by 2:00 p.m. local time in Las Vegas, NV on July 15, 2008 from the U.S. Postal Service or other commercial delivery service. Applications submitted electronically through grants.gov must be received by grants.gov by 5:00 p.m. EDT on July 15, 2008.
Archive Date:	(To be completed by GAD)
Category of Funding Activity:	Environment
Anticipated Number of Awards:	1
Anticipated Total Program Funding:	$2,500,000
Award Ceiling:	$2,500,000
Award Floor:	$2,500,000
CFDA Number:	66.511 ORD Consolidated Research
Cost Sharing or Matching Requirement:	None
Geospatial Information	It is anticipated that the agreement that is awarded will not involve or relate to geospatial information.

Eligible Applicants

Programs under CFDA 66.511 are available to each State, territory and possession, and Tribal nation of the United States, including the District of Columbia, for public and private State universities and colleges, hospitals, laboratories, State and local government departments, and other public or private nonprofit institutions and in some cases, individuals who have demonstrated unusually high scientific ability. Profit-making firms are not eligible to receive awards. Eligible nonprofit organizations include any organizations that meet the definition of nonprofit in OMB Circular A-122. However, nonprofit organizations described in Section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities as defined in Section 3 of the Lobbying Disclosure Act of 1995 are not eligible to apply. Universities and educational institutions must be subject to OMB Circular A-21.

Federal Agency Name

U.S. Environmental Protection Agency, Office of Research and Development, National Exposure Research Laboratory, Human Exposure and Atmospheric Sciences Division
Attn: Raina Porras, 944 E. Harmon Avenue, Las Vegas, NV 89119

Description

The U.S Environmental Protection Agency (EPA) is seeking applications proposing an observational exposure measurement study to identify and characterize the determinants of exposure for early lifestages (i.e., very young children <3 years of age) to chemicals in their environment. Very young children represent an important lifestage that may be more vulnerable to chemicals in the environment because they are physiologically and behaviorally different from adults. The importance of lifestage is recognized in the US EPA's document entitled *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants,* that recommends a set of childhood age groupings based on the current understanding of the differences in lifestage behavior, anatomy, and physiology (US EPA, 2005). For very young children, early lifestage age groups identified in this guidance include: birth to <1 month, 1 to <3 months, 3 to <6 months, 6 to <12 months, 1 to <2 years, and 2 to <3 years. Very young children may be particularly susceptible to exposures to pesticides used indoors and to chemicals present in consumer products used indoors, but the exposure factors for this population have not been well-characterized. The routes and pathways by which very young children may come into contact with pollutants, particularly the dermal and indirect (non-dietary) ingestion routes of exposure, are also not well-characterized or understood. There are many factors related to human behaviors and characteristics that affect exposure to chemicals in homes, child care centers, schools, public access buildings, and outdoors. The EPA Exposure Factors Handbook provides recommended values for exposure factors based on data from a number of key studies (US EPA, 1997). The EPA Child-Specific Exposure Factors Handbook contains recommendations specific to exposure assessments for children, but the data are limited for a number of key factors (US EPA, 2002). Additional data on the determinants of exposure for very young children (under 3 years of age) are needed to fully understand their exposures.

Observational exposure measurement studies are important for collecting data on the determinants of exposure. These studies are performed to collect data on chemical exposures under "real-world" conditions (i.e., in the environments that people occupy while they go about their normal activities) and do not involve additional exposures to the chemicals being studied due to participation in the study. Data are collected to determine what chemicals people contact, the concentrations of the chemicals in various media, the predominant routes and pathways of exposure, and the most important factors that impact exposure. Data collected in observational human exposure measurement studies are critical to understanding how chemical stressors affect the susceptible early lifestages and how developmental and lifestage factors, personal activities, and characteristics of the microenvironments that these groups occupy impact their exposures. The data collected in observational studies enhance public health by reducing uncertainties in exposure and risk assessments and by providing information that can be used to develop risk mitigation strategies and methods. But observational human exposure measurement studies are complex in their design and implementation. There are many scientific and ethical considerations to be addressed in these studies by the research team, including, but not limited to, those related to recruitment, retention, participant compensation, third-party issues, researcher-participant interactions, researcher-community interactions, communications,

interventions, and education. Researchers in EPA have developed a document on scientific and ethical approaches for observational exposure studies that is available to the research team conducting work under this agreement. Observational exposure measurement studies involving human participants conducted under this announcement must comply with the requirements of 40 CFR Part 26, including the special requirements for observational studies involving children and/or pregnant women found in Subparts C and D. In accordance with EPA policy, observational human exposure measurement studies require Institutional Review Board approval for the participating organizations and certification by the EPA's Human Subjects Research Review Official.

The goal of this research is to design and implement an innovative observational exposure measurement study that will further our understanding of the determinants of exposure, especially as they relate to dermal and indirect (e.g., non-dietary) ingestion exposures, for very young children to chemicals, including pesticides, in their residential environment in order to improve exposure and risk assessments and to develop better exposure mitigation strategies.

Application Materials

You may submit either a printed application or an electronic application (but not both) for this announcement. The printed application must be submitted to Raina Porras, 944 E. Harmon Avenue, Las Vegas, NV 89119, by the closing date and time. To apply electronically, the electronic application package available through the http://www.grants.gov/ web site must be used. If your organization is not currently registered with Grants.gov, you need to allow approximately one week to complete the registration process. This registration, and electronic submission of your application, must be performed by an appropriate representative of your organization.

Agency Contact Person for Electronic Access Problem

Walter Stutts, phone: (513) 569-7487 email: stutts.walter@epa.gov

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FULL TEXT OF ANNOUNCEMENT

I. Funding Opportunity Description

Title of Assistance Opportunity: "OBSERVATIONAL STUDIES TO CHARACTERIZE THE DETERMINANTS OF EXPOSURE TO CHEMICALS IN THE ENVIRONMENT FOR EARLY-LIFESTAGE AGE GROUPS"

Background

The mission of the U.S. Environmental Protection Agency (EPA) is to protect public health and safeguard the environment. Risk assessment and risk management are an integral part of this mission. EPA's Office of Research and Development (ORD) Human Health Research Program has developed a strategic approach for research to improve human health risk assessment and risk management. A major objective of the program is to reduce uncertainties in the risk assessment process by providing a greater understanding of the fundamental determinants of exposure. Variability in exposure is a key uncertainty in human health risk assessments. Legislation, including the Safe Drinking Water Act Amendments of 1996 and the Food Quality Protection Act of 1996, has called on the EPA to consider potentially susceptible populations in the risk assessment process. Research to understand differential exposures to early lifestages (e.g., very young children <3 years of age) is an important research area for the Agency.

The US EPA's guidance document entitled *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* recommends a set of childhood age groupings based on the current understanding of the differences in lifestage behavior, anatomy, and physiology that can serve as a starting set for consideration by researchers and risk assessors (US EPA, 2005). These early lifestage age groups are birth to <1 month, 1 to <3 months, 3 to <6 months, 6 to <12 months, 1 to <2 years, and 2 to <3 years.

For the scientific community to address this priority research area, data are needed that identify the most important determinants of exposure (chemical sources, environmental concentrations, routes and pathways of exposure, and exposure factors) for early lifestages (e.g., very young children <3 years of age). The scientific community recognizes young children as an important susceptible subpopulation within the early lifestage age groups because their physiological characteristics may influence their exposures to chemicals in their environment either by affecting their rate of contact with various media or altering the exposure-uptake relationship. Children's behavior and the way that they interact with their environment may also influence their potential exposures to chemicals in their environment. Very young children may have higher exposures to chemicals due to their mouthing activities, crawling, and extensive contact with indoor surfaces that may be contaminated with chemicals, such as pesticides, phthalates, brominated flame retardants, perfluoroalkyl compounds, and other chemicals that may be present in the indoor environment due to the presence and use of consumer products.

There are many factors related to children's behaviors and characteristics that affect their exposures to chemicals. Developmental stage, physical activity, diet and eating habits, gender,

socioeconomic status, and race/ethnicity are all factors that have been identified as potentially influencing a child's potential exposure to pesticides (Cohen Hubal *et al.*, 2000a, b). Understanding these factors is important in evaluating a child's aggregate exposure to pesticides and other chemicals and identifying which factors most influence a child's potential exposure to pesticides. In 2001, the EPA published the report entitled *Draft Protocol for Measuring Children's Non-Occupational Exposure to Pesticides by all Relevant Pathways* which provides guidance on the data needs and requirements for conducting an aggregate exposure assessment for children (US EPA, 2001). The EPA Exposure Factors Handbook provides recommended values for exposure factors for the general population based on data from the published literature (US EPA, 1997). However, data for some exposure factors are limited. The EPA Child-Specific Exposure Factors Handbook also contains recommendations specific to exposure assessments for children but, again, the data are limited for some exposure factors, and there is a reasonable amount of uncertainty for a number of factors (US EPA, 2002). The lack of data needed for exposure and risk assessments means that the scientific community must rely on default parameters that may not be most appropriate. The routes and pathways of exposure for very young children, particularly the dermal and indirect (non-dietary) routes of exposure are not well-characterized and are poorly understood. Cohen Hubal et al. (2000a) identified dermal and non-dietary ingestion exposures as two critical areas for further study of children's exposures. Indirect (non-dietary) ingestion may be particularly important for very young children who play on floors and more frequently contact surfaces that may be contaminated with chemicals. Diet has also been identified as an important route of exposure for children. In the Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) study, diet accounted for nearly 60% of the exposures for children (aged 2 to 5 years) in Ohio for *cis*-permethrin, a current-use pyrethroid pesticide. But indirect ingestion was also very important, accounting for 39% of exposure for the children. Inhalation only accounted for 4% of the children's exposures (Morgan et al., 2004). Dermal exposure was not estimated in this study. Lu et al. (2006a) showed that diet was an important route of exposure for young children to the agricultural pesticides chlorpyrifos and malathion by substituting an "organic" diet for a conventional diet. They reported that the median urinary concentrations of the specific metabolites for chlorpyrifos and malathion decreased to non-detectable levels after the introduction of the organic diet and remained at non-detectable levels as long as the child continued on the "organic" diet. However, Lu and colleagues (2006b) used the same protocol for a study of pyrethroid pesticides and concluded that residential pesticide use, not diet, was the most important factor influencing a child's potential exposure to pyrethroid pesticides. Their study suggested that the indirect ingestion and/or dermal routes of exposure were very important. Research by Shalat et al. (2003), Black et al. (2005), and Hore et al. (2006) have also suggested that the dermal and indirect ingestion routes of exposure were important. Furthermore, modeling efforts by Zartarian et al. (2000) also suggested that dermal exposure was important for young children. To reduce uncertainty for exposure assessments for children, particularly very young children, additional data on exposure factors are needed, particularly for the indirect ingestion and dermal routes of exposure.

Data on exposure factors are critical for an improved understanding of why and how early lifestages come into contact with chemicals in their environment. Observational human exposure measurement studies are needed for collection of additional data on the factors impacting exposures of very young children. Observational exposure measurement studies are intended to collect data on exposures of study participants under "real-world" conditions, i.e., in the participants' everyday

environment as they pursue their normal daily activities. These studies do not involve additional exposures to the chemicals being studied due to participation in the observational studies. The Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) study is an excellent example of how observational exposure measurement studies have improved our understanding of children's exposures to chemicals in homes and child care centers. This observational study involved measurements of 50 different chemicals, including organochlorine pesticides, organophosphate pesticides, pyrethroid pesticides, polycyclic aromatic hydrocarbons (PAHs), phthalates, and selected pesticide metabolites (Wilson et al., 2004). Multimedia measurements were performed to identify the most important routes and pathways of exposure, which differed for different chemical classes. The study collected data on a variety of exposure factors (Morgan et al., 2004). Results from CTEPP also showed that 3,5,6-trichloro-2-pyridinol (TCPy), a degradation product of chlorpyrifos, was not a good biomarker of exposure to the pesticide because TCPy was present, not only in urine samples, but also in food and environmental media to which the children were exposed (Morgan et al., 2005).

Other examples of observational exposure measurement studies that have improved our understanding of children's exposures to chemicals in their homes include studies conducted by researchers in the jointly-funded EPA/National Institute of Environmental Health Sciences (NIEHS) Children's Research Centers. Whyatt and colleagues (2003) enrolled 230 mother and newborn pairs into the Columbia Center for Children's Environmental Health prospective cohort study. Personal air samples collected from the mothers during pregnancy contained eight different pesticides (Whyatt et al., 2002). Numerous pesticides were also detected in the plasma samples. Maternal and cord plasma levels were correlated, and personal air and maternal and/or cord plasma samples were also correlated. Whyatt and colleagues (2003) concluded that pesticide exposure during pregnancy is frequent and that the pesticides are readily transferred to the developing fetus during pregnancy. Researchers at the University of Washington have conducted observational studies to compare exposures of farmworker children and children in an urban area (Fenske et al., 2000a, b; Loewenherz et al., 1997; Lu et al., 2000; Simcox et al., 1995). Although they reported higher levels of metabolites of organophosphate pesticides in children of pesticide applicators, median dimethylthiophosphate concentrations for Seattle children and farmworker children did not differ significantly, suggesting that dietary exposure is important and that the determinants of exposure need to be more adequately defined. Bradman et al. (2006) also conducted an observational study of young children's exposures to pesticides. They reported on the applicability of their field sample collection protocols to assess young children's exposures to pesticides. Four of five pesticides were positively correlated among the house dust, sock, and union suit samples (Bradman et al., 2006), reinforcing that dermal and indirect ingestion exposures may be important routes of exposure.

The use of biomarkers as indicators of exposure has increased in recent years. The Centers for Disease Control and Prevention (CDC) perform an extensive set of analyses in the National Health and Nutrition Examination Survey (NHANES; http://www.cdc.gov/nchs/nhanes.htm). Numerous epidemiological studies and recent observational studies have included biomonitoring (Bouvier et al., 2005). Biomarkers of exposure can be used to show that humans came into contact with a chemical at some point in time. However, without the accompanying environmental measurement data, it is extremely difficult to identify the most important exposure factors, as well as the important sources, pathways, and routes of human exposure to the chemicals. To make

improvements in the way we quantitatively estimate human exposure to chemicals, it is important to simultaneously collect environmental measurement data, activity patterns, exposure factors, and biomarker data.

Observational human exposure studies are complex. There are many scientific and ethical considerations to be addressed in the design and implementation of these studies, including, but not limited to, recruitment, retention, participant compensation (both monetary and non-monetary), communication between researchers/participants/community/stakeholders, intervention, and education. Researchers within and outside of the Agency have recognized the need to ensure that these studies are of the highest scientific quality and meet the highest ethical standards. The EPA held an Expert Panel Workshop (November 28-29, 2006) on *State-of-the-Science Approaches for Observational Exposure Measurement Studies* (http://www.epa.gov/nerl/sots/) to gather background information for an EPA document that provides information on the most up-to-date scientific and ethical approaches for the design and implementation of these studies. This document, *Scientific and Ethical Approaches for Observational Exposure Studies*, is available to the research community (http://www.epa.gov/nerl/sots/) . Research conducted under this announcement must be consistent with the approaches set forth in this document. In addition, all observational studies conducted under this announcement must comply with the 40 CFR 26, including the special requirements for observational studies involving children and/or pregnant women found in Subparts C and D. In accordance with EPA policy, observational human exposure measurement studies require Institutional Review Board approval for all participating organizations, as well as certification by the EPA's Human Subjects Research Review Official.

NERL anticipates a collaborative effort under this agreement with experts in the field of exposure assessment to address the uncertainties associated with measuring and/or assessing exposure for very young children, particularly in relation to exposures to pesticides used indoors and to other semi-volatile persistent and non-persistent organic chemicals that may be present in the indoor environments that very young children occupy. The goal of this work is to identify the activity factors and other factors (i.e., determinants of exposure) related to lifestage affecting exposures of very young children in the U.S. to pesticides and other chemicals. Research conducted under this agreement should also assess the utility of biomarkers of exposure for improved characterization and understanding of human exposure to selected classes of chemicals in the environment, particularly pesticides currently used indoors. It is anticipated that the research conducted under this agreement will involve innovative approaches for the design and implementation of observational exposure measurement studies and will incorporate strategies and methods for mitigation of exposures measured in the studies.

Funding Priorities/Focus: The purpose of this RFA is to solicit applications for a cooperative agreement to improve the understanding of the factors that are most important for exposures of very young children to pesticides and other organic chemicals present in indoor environments. The proposed research will support EPA's strategic goals by reducing uncertainty in exposure assessments and risk assessments for susceptible early lifestages. Examples of specific activities are listed below. Investigators responding to this RFA however, should not limit themselves to these activities. While not absolutely required **(unless identified as Other Threshold Eligibility Criteria in Section III**), it is anticipated that investigators responding to this RFA will include all of the

activities listed, as well as other activities they deem necessary to meet the goals of this assistance opportunity. The activities listed below are considered of equal priority for meeting these goals.

- Develop hypotheses that will be tested to determine what factors have the greatest impact on exposures of very young children to pesticides and other organic chemicals in indoor environments, particularly as they relate to dermal and indirect ingestion exposure.
- Develop innovative approaches for testing these hypotheses.
- Develop innovative approaches for conducting observational exposure studies involving very young children.
- Incorporate state-of-the-science approaches to address ethical considerations in design and implementation of the study.
- Develop innovative approaches and methods for estimating dermal and indirect ingestion exposures for very young children. **(Threshold eligibility criterion – see Section III.)**
- Identify and evaluate factors that may result in differential exposures and increased susceptibility for very young children to pesticides and other chemicals in the home environment.
- Evaluate routes and pathways of exposure for very young children in the home environment.
- Evaluate whether the activities and behaviours of very young children bring them into more or less contact with pollutants in their environment, when compared to older children and adults, and relate these activities to developmental stage and/or age including the following age groups: birth to <1 month, 1 to <3 months, 3 to <6 months, 6 to <12 months, 1 to <2 years, and 2 to <3 years. **(Threshold eligibility criterion – see Section III.)**
- Use biomarkers of exposure to evaluate exposure factors.
- Evaluate the use and interpretation of biomarkers of exposure for very young children, using appropriate algorithms and models to estimate aggregate and cumulative exposures to pesticides based on measurements of target chemicals in environmental media and diet for comparison to estimates of exposure based on biomarkers. **(Threshold eligibility criterion – see section III.)**
- Develop innovative approaches for maximizing the benefit of the observational study for the study participants and their community.

Additionally, investigators responding to this RFA should consider the following activities when responding to this assistance opportunity.

- Apply the community-based participatory research approach to an observational study of children's exposures to pesticides and other chemicals in the home environment.
- Develop innovative approaches for working with communities on observational measurement studies that address exposures of early lifestages to specific classes of chemicals, including pesticides.
- Develop innovative approaches for incorporating exposure mitigation into observational studies.

Environmental Results: This RFA seeks applications that will advance the following goals/objectives as identified in EPA's 2006 Strategic Plan (http://www.epa.gov/cfo/plan/2006/entire_report.pdf):

Goal: 4 - Healthy Communities and Ecosystems
Objective: 4.4 - Enhance Science and Research
Long Term Goals: HH-2 Aggregate Exposures/Risks, HH-3 Cumulative Exposures/Risks

EPA's human health research represents the Agency's only comprehensive program to address the limitations in human health risk assessment. EPA's human health research focuses on a unified risk assessment approach that incorporates biological modes of toxicity, aggregate and cumulative exposures, susceptible subpopulations, and evaluations of public health outcomes resulting from risk management actions.

Outputs expected from the research funded under this agreement include:

- Identification and evaluation of the most important determinants of exposure for different early lifestages,
- Databases of chemical concentrations in environmental media, diet, and biological samples from an observational study,
- Innovative approaches, protocols, and tools for measuring children's exposures via different routes and pathways,
- Innovative approaches, protocols, and tools for conducting community-based observational exposure studies,
- Data to improve the understanding and interpretation of biomarkers of exposure measurements,
- Innovative approaches, protocols, and tools for education and mitigation related to the home environment,
- Innovative and state-of-the-science approaches, protocols, and tools to address scientific and ethical considerations in the design and implementation of the observational exposure study, and
- Peer-reviewed scientific journal articles that effectively disseminate the results of the study to the scientific community.

The anticipated outcomes from this research include:

- Improved understanding of the determinants of exposure for very young children, particularly for dermal and indirect ingestion routes of exposure,
- Less reliance on default assumptions and reduced uncertainty of exposure and risk assessments for very young children as a result of improved understanding of the factors impacting exposures for early lifestages to chemicals, such as pesticides and chemicals from consumer products present in indoor environments.
- Improved education strategies for reducing exposures of children to chemicals in the indoor environment, and
- Reduction or mitigation of children's exposures to chemicals due to improved information on exposure factors.

Note to applicant: The term "output" means an environmental activity or effort, and associated work projects, related to a specific environmental goal(s), (e.g., testing a new methodology), that will be produced or developed over a period of time under the agreement. The

term "outcome" means the result, effect, or consequence that will occur from the above activities that is related to an environmental, behavioral, or health-related objective.

Statutory Authority for Award of Assistance: This research is authorized under the Clean Air Act, Section 103, the Clean Water Act, Section 104, the Safe Drinking Water Act, Section 1442, and the Federal Insecticide, Fungicide, and Rodenticide Act, Section 20. The Clean Air Act authorizes the use of grants by EPA to promote research in the prevention and control of air pollution. The Clean Water Act authorizes the use of grants by EPA for research, investigations, experiments, training, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, reduction, and elimination of pollution. The Safe Drinking Water Act, as amended, authorizes EPA to conduct studies to identify subpopulations at greater risk (e.g., infants, children) of adverse health effects from exposure to contaminants in drinking water. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Section 20 authorizes EPA to undertake research (including by grant to universities) into integrated pest management. Monitoring of air, soil, water, man, plants and animals is one component of this section.

Geospatial Information: It is anticipated that the agreement that is awarded will not involve or relate to geospatial information.

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II. Award Information

Anticipated Amount of Individual Award: $2,500,000

Anticipated Number of Awards: One

EPA reserves the right to make additional awards under this announcement, consistent with Agency policy and guidance, if additional funding becomes available after the original selections are made. Any additional selections for awards will be made no later than 6 months after the original selection decisions.

Anticipated Funding: The EPA anticipates fully funding this project upon award of the agreement.

Anticipated Project Period: 12/1/08 to 11/30/12

Supplemental Applications: Applications for supplemental awards of existing EPA assistance agreements will not be eligible to compete for this assistance opportunity.

Type of Award: The Agency anticipates the award of a cooperative agreement.

Anticipated Federal Involvement: EPA and the Project Officer for this assistance agreement anticipate substantial involvement in the implementation of the research as follows:

1. Discuss the specific approach for the study with the members of the project team.

2. Share data with the project team for use in finalizing the approach for the study design of the observational exposure measurement study.

3. Provide technical input to the details of the study design for the observational exposure measurement study for early lifestages.

4. Coordinate extramural research with in-house research activities.

5. Provide technical input on a regular basis through scheduled meetings and monthly conference calls.

6. Collaborate with the project team to identify milestones and discuss progress.

7. Participate in outreach to, and interactions with, the communities in which the observational study will be performed.

8. Obtain approval from the Office of Management and Budget for Information Collection Requests (ICR) submitted under the Paperwork Reduction Act.

9. Obtain approval from EPA for the Human Studies Research Protocol.

10. Participate in field data collection activities during the observational study.

11. Provide in-kind support in the form of chemical analyses for perfluorinated chemicals, brominated diphenyl ethers, and/or pyrethroid pesticides in media such as housedust, surface wipes, and air. Measurement results will be provided to the grantee for their use in analyses of the study results.

12. Participate in the data analysis and reporting of the analyzed multimedia samples.

13. Participate in the preparation and review (to include co-authorship) of journal articles and

reports.

III. Eligibility Information

Eligible Applicants: Programs under CFDA 66.511 are available to each State, territory and possession, and Tribal nation of the United States, including the District of Columbia, for public and private State universities and colleges, hospitals, laboratories, State and local government departments, and other public or private nonprofit institutions and, in some cases, individuals who have demonstrated unusually high scientific ability. Profit-making firms are not eligible to receive awards. Eligible nonprofit organizations include any organizations that meet the definition of nonprofit in OMB Circular A-122. However, nonprofit organizations described in Section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities as defined in Section 3 of the Lobbying Disclosure Act of 1995 are not eligible to apply. Universities and educational institutions must be subject to OMB Circular A-21.

National laboratories funded by Federal Agencies (Federally-Funded Research and Development Centers, "FFRDCs") may not apply. FFRDC employees may cooperate or collaborate with eligible applicants within the limits imposed by applicable legislation and regulations. They may participate in planning, conducting, and analyzing the research directed by the applicant, but may not direct projects on behalf of the applicant organization. The institution, organization, or governance receiving the award may provide funds through its assistance agreement from the EPA to an FFRDC for research personnel, supplies, equipment, and other expenses directly related to the research.

Federal Agencies may not apply. Federal employees are not eligible to serve in a principal leadership role on an assistance agreement, and may not receive salaries or augment their Agency's appropriations in other ways through awards made under this program.

The applicant institution may enter into an agreement with a Federal Agency to purchase or utilize unique supplies or services unavailable in the private sector. Examples are purchase of satellite data, census data tapes, chemical reference standards, analyses, or use of instrumentation or other facilities not available elsewhere. A written justification for federal involvement must be included in the application. In addition, an appropriate form of assurance that documents the commitment, such as a letter of intent from the Federal Agency involved, should be included.

Cost Sharing Requirements: Institutional cost-sharing is not required. However, if the applicant intends to cost-share, a brief statement concerning cost-sharing should be added to the budget justification, and estimated dollar amounts must be included in the appropriate categories in the budget table. The amount of cost sharing proposed (if any) will not result in additional points for any applicant, but will be considered in the evaluation of the reasonableness and realism of the overall budget.

Other Threshold Eligibility Criteria:

Administrative Eligibility Criteria:

a. Proposals must substantially comply with the proposal submission instructions and requirements set forth in Section IV of this announcement or else they will be rejected. However, where a page limit is expressed in Section IV with respect to the proposal (or parts of the proposal), pages in excess of the page limitation will not be reviewed.

b. In addition, proposals must be received by the EPA or received through **www.grants.gov,** as specified in Section IV of this announcement, on or before the proposal submission deadline published in Section IV of this announcement. Applicants are responsible for ensuring that their proposal reaches the designated person/office specified in Section IV of the announcement by the submission deadline.

c. Proposals received after the submission deadline will be considered late and returned to the sender without further consideration unless the applicant can clearly demonstrate that it was late due to EPA mishandling. For hard copy submissions, where Section IV requires proposal receipt by a specific person/office by the submission deadline, receipt by an agency mailroom is not sufficient. Applicants should confirm receipt of their proposal with Ms. Raina Porras as soon as possible after the submission deadline—failure to do so may result in your proposal not being reviewed.

Relevance Eligibility Criteria: Proposals that are found administratively acceptable will be subjected to a review for relevancy to EPA's mission to support advancement of environmental science. Proposals will be rejected if they are found to lack relevance. Examples of proposals that lack relevance include:

1. Proposal is deficient technically with no chance for consideration.
2. Proposal fails to advance the objectives stated in the solicitation even if successfully performed.
3. Proposal essentially duplicates research already completed or underway.
4. Proposal fails to demonstrate a public purpose of support and stimulation; (e.g., it implies the primary purpose is to provide direct support to the Federal government).

Funding Priorities/Focus Eligibility Criteria: Under the Funding Priorities/Focus discussion in Section I, a number of examples of activities are described that would likely be included in an applicant's proposal. While it is not required that all of the activities listed be included in a proposal, it is required that each proposal include the following three activities. Proposals that fail to include a discussion of each of these three activities will not be considered for award.

- Develop innovative approaches and methods for estimating dermal and indirect ingestion exposures for very young children.

- Evaluate whether the activities and behaviours of very young children bring them into more or less contact with pollutants in their environment, when compared to older children and adults, and relate these activities to developmental stage and/or age including the following age groups: birth to <1 month, 1 to <3 months, 3 to <6 months, 6 to <12 months, 1 to <2 years, and 2 to <3 years.

- Evaluate the use and interpretation of biomarkers of exposure for very young children, using

appropriate algorithms and models to estimate aggregate and cumulative exposures to pesticides based on measurements of target chemicals in environmental media and diet for comparison to estimates of exposure based on biomarkers.

Applications will be reviewed for threshold eligibility purposes prior to initiation of the technical and programmatic reviews under Section V. **Applicants deemed ineligible for funding consideration as a result of the threshold eligibility review will be notified within 15 calendar days of the ineligibility determination.**

IV. Application and Submission Information

Applicants must submit a complete, detailed application to include all of the documents described in Section A below regardless of the mode of transmission. Additional guidance on completing the documents is available at EPA's Office of Grants and Debarment (http://www.epa.gov/ogd/). Applicants may submit either a hard-copy printed application or an electronic application through grants.gov (but not both) for this announcement. Applications may not be submitted via email. Instructions for both forms of submission follow.

A. Application Materials

The application is made through submission of the materials described below. ***It is essential that the application contain all information requested and be submitted in the formats described.*** The application must contain the following items:

1. Application For Federal Assistance (SF-424). Complete the form. There are no attachments. Please be sure to include the organization fax number and email address in Block 5 of the SF-424.

This form will be the ***first page*** of the application. Instructions for completion of the SF-424 are included with the form. (However, note that EPA requires that the entire requested dollar amount appear on the 424, not simply the proposed first year expenses.) The form must contain the original (or electronic) signature of an authorized representative of the applying institution. Please note that both the Principal Investigator and an administrative contact are to be identified in Section 5 of the SF-424. The applicant's DUNS number must be included. (See Section VIII for instructions on obtaining a DUNS number.)

2. Budget Information for Non-Construction Programs (SF-424A). Complete the form. There are no attachments. At a minimum, complete Section B- Budget Information and Section F- Other Budget Information. The total amount of federal funding requested for the project period should be shown on line 5(e) and on line 6(k) of SF-424A. If indirect costs are included, the amount of indirect costs should be entered on line 6(j). The indirect cost rate (i.e., a percentage), the base (e.g., personnel costs and fringe benefits), and the amount should also be indicated on line 22.

3. Key Contact List. EPA Key Contacts Form 5700-54 should include the Principal, Co-

Investigators, and administrative contacts. A copy of this form should also be completed for major sub-agreements (contacts at the institutions of primary co-investigators).

4. Project Narrative and Supporting Documentation

The Project Narrative and Supporting Documentation should be readable in PDF, MS Word or Word Perfect WP6/7/8 for Windows and consolidated into a single file.

a. The project narrative is the technical proposal that discusses the technical approach and organizational capabilities for accomplishing the goals stated under the Funding Priorities/Focus in Section I. It is critical that the applicant demonstrate knowledge and experience of **state-of-the science approaches for designing and implementing observational exposure measurement studies of very young children to chemicals in the environment, including current-use indoor pesticides with emphasis on the dermal and indirect ingestion routes of exposure.**

The project narrative must describe the proposed hypotheses to be tested for identifying the most important determinants of exposure for very young children to pesticides and other organic chemicals in residential environments, particularly as they relate to dermal and indirect ingestion routes of exposure. The narrative must describe the innovative approaches that will be used to test these hypotheses, the feasibility of the proposed approaches for testing the hypotheses, and the analyses to be performed to evaluate the importance of factors that impact young children's exposures to chemicals. The proposal must describe the scope and the general approach of the study. The narrative must describe what measurements and time/location/activity data should be included in the observational study in order to test the proposed hypotheses and improve understanding of chemical sources, routes and pathways of exposure, and exposure factors for very young children's exposures. It must explain how data and information collected in the observational exposure measurement study can be used to also improve the understanding of the use of biomarkers of exposure (e.g., pesticide metabolites measured in biological samples). It must describe how the recipient intends to process, analyze, interpret, and report data from the observational exposure measurement study to meet the goals of the agreement. Although detailed information, such as would be included in a study design, is not necessary, sufficient information on the proposed approach must be included so that the soundness of the approach and the likelihood of success can be evaluated.

Because of the complexity of observational exposure measurement studies with respect to both scientific and ethical considerations, the recipient must describe how they will ensure that the approaches used in this agreement are the most up-to-date and how they will ensure that the study meets the highest scientific and ethical standards. The narrative must describe how the recipient will identify and implement innovative approaches for conducting an observational exposure measurement study. The narrative must also describe how innovative approaches for incorporating exposure mitigation will be incorporated into the observational exposure measurement study.

The proposal must describe the community in which the recipient intends to perform the observational exposure measurement study; previous research performed by the recipient in the community; the existing researcher/community relationships with regard to environmental, exposure, and/or public health research conducted in the community; how these relationships were developed;

and how these relationships will be maintained/developed for future research, including observational exposure measurement studies. The narrative must describe how the recipient will identify and select a study cohort within this community, including the demographics of the cohort and the proposed selection criteria. The narrative must provide evidence that the characteristics of the proposed cohort, including the size of the cohort, are adequate for testing the hypotheses (e.g., is there sufficient variability in the anticipated environmental media concentrations and potential exposures to be able to identify and measure factors impacting exposure; what is the likelihood of detecting the target analytes in diet and environmental media samples; will the target analytes be detected in a sufficient number of media to perform aggregate exposure assessments and estimates of dose that can be compared to biomarker measurements, etc.?).

The narrative must identify the anticipated environmental outputs and associated outcomes, and include a plan for tracking and measuring the success in achieving the same. Key personnel must be identified with their roles and commitment to the project described. Include citations of relevant manuscripts, reports, etc. produced by the proposed key personnel under other similar projects that would demonstrate their expertise, experience and knowledge of i) design and implementation of observational human exposure studies, ii) the community-based participatory research model, conducting research in communities, and developing and maintaining interactions with communities, iii) susceptible early lifestages and factors affecting differential exposures and vulnerability, iv) methods (sampling and analysis) for measurements of chemicals in observational studies, v) potential biomarkers of exposure and approaches for their collection and interpretation of the data, and vi) project management and leadership of interdisciplinary teams, particularly management of cross-disciplinary projects that encompass research in communities. Describe the non-personnel resources that are available or will be made available to complete the project, including measurement instrumentation, analytical instrumentation, laboratory facilities, field support hardware and instrumentation, computer facilities, etc. In developing the project narrative, the applicant must focus on the first three Technical Evaluation Criteria set forth in Section V and structure the proposal to address each in the order listed. The fourth Technical Evaluation Criterion will evaluate the Quality Management Plan which will be a separate document from the project narrative as discussed below.

The project narrative, including those submitted electronically, must be submitted in English and must not exceed fifty (50) consecutively numbered (bottom center) 8.5X11-inch pages of single-spaced, standard 12-point type with 1-inch margins. This page limitation shall include all text, tables, figures, attachments, and appendices. It does not include references or the materials requested below in items b, c, d, or e.

b. The Quality Management Plan must describe the quality system in terms of management and organizational structure, policy and procedures, personnel qualifications and training; procurement of items and services; documentation and records; computer hardware and software; planning; implementation of work processes; assessment and response; and quality improvement. Thus, the Quality Management Plan may be viewed as the "umbrella" document under which individual projects are conducted. The Quality Management Plan is used to demonstrate conformance to Part A requirements of ANSI/ASQC E4-1994. The Quality Management Plan must be approved and signed by the senior management of the organization. For more information, go to http://www.epa.gov/quality.

c. A demonstration of the applicant's programmatic capability (separate from the Project Narrative) to successfully complete the proposed project, to include documentation of past performance in meeting the reporting requirements of current or recently completed assistance agreements. Applicants should at a minimum submit a list of projects of similar size, scope and relevance to the proposed project that the applicant's proposed PI has undertaken in the past five years under assistance agreements (assistance agreements include grants and cooperative agreements but not contracts) awarded by Federal and/or non-federal governmental agencies. Include the title, the Principal Investigator, the total amount funded, the project period, a brief (1-3 lines) description of the project, and the record of resulting peer reviewed publications. Describe how you documented and/or reported on whether you were making progress towards achieving the expected results (e.g., outputs and outcomes) under those agreements. If you were not making progress, please indicate whether, and how, you documented why not. Provide a point of contact in the primary sponsor's organization with email address and telephone. The information provided will be used by the Agency in conjunction with other readily available information to evaluate the applicant's programmatic capability with respect to past performance. The Agency, as a part of the evaluation process, may contact the referenced sponsor to obtain more detailed information of the applicant's recent past performance in completing projects of similar size, scope and relevance and in meeting the reporting requirements of those agreements.

d. Budget Narrative includes detailed, itemized budget estimates for the project that is broken down into direct labor, fringe benefits, equipment, travel, other direct costs and overhead with summaries for each year and the total for the entire project. If a subagreement is included in the application, provide a separate budget for the subagreement in the same format if the subagreement is greater than $25k.

If amounts are budgeted for subcontracts, provide a description of the work that will be subcontracted and an explanation of why it must be subcontracted. Indicate whether the subcontracts will be awarded competitively or if not, what justification exists to make a non-competitive award. Any budget that includes amounts for subcontracts of 40% or more of the total direct costs will be subject to special review. Refer to Section IV.F, Partnerships, for a further discussion of proposed subcontracts.

Please note that institutional cost-sharing is not required. However, if you intend to cost-share, a brief statement concerning cost-sharing should be added to the budget justification, and estimated dollar amounts must be included in the appropriate categories in the budget table.

Describe the basis for calculating the personnel, fringe benefits, travel, equipment, supplies, contractual support, and other costs identified in the itemized budget and explain the basis for their calculation. (Special attention should be given to explaining the "travel," "equipment," and "other" categories.). For any proposed equipment, identify any tangible non-expendable personal property to be purchased which has an estimated cost of $5,000 or more per unit and a useful life of more than one year. (Personal property items with a unit cost of less than $5,000 are considered supplies.) Tips for preparing the budget support can be found at http://www.epa.gov/ogd/recipient/tips.htm.

e. Biographical Sketches - 2-page curriculum vitae should be included for the Principal Investigator, co-principal investigator(s), and any other key personnel identified in the proposal.

B. Submission Instructions for Electronic Applications Using Grants.gov

The electronic submission of your application must be made by an official representative of your institution who is registered with Grants.gov and is authorized to sign applications for Federal assistance. For more information, go to http://www.grants.gov and click on "Get Registered" on the left side of the page. *Note that the registration process may take a week or longer to complete.* If your organization is not currently registered with Grants.gov, please encourage your office to designate an AOR and ask that individual to begin the registration process as soon as possible.

To begin the application process under this grant announcement, go to http://www.grants.gov and click on the "Apply for Grants" tab on the left side of the page. Then click on "Apply Step 1: Download a Grant Application Package" to download the compatible **Adobe** viewer and obtain the application package. **To apply through grants.gov you must use Adobe Reader applications and download the compatible Adobe Reader version (Adobe Reader applications are available to download for free on the Grants.gov website. For more information on Adobe Reader please visit the Help section on grants.gov at** http://www.grants.gov/help/help.jsp or http://www.grants.gov/aboutgrants/program_status.jsp).

Once you have downloaded the viewer, you may retrieve the application package by entering the Funding Opportunity Number, **EPA-ORD-08-27294**, or the CFDA number that applies to the announcement (CFDA 66.511), in the appropriate field. You may also be able to access the application package by clicking on the Application button at the top right of the synopsis page for this announcement on http://www.grants.gov (to find the synopsis page, go to http://www.grants.gov and click on the "Find Grant Opportunities" button on the left side of the page and then go to Search Opportunities and use the Browse by Agency feature to find EPA opportunities).

Application Submission Deadline: Your organization's AOR must submit your complete application electronically to EPA through Grants.gov (http://www.grants.gov) no later than 5pm EDT on July 15, 2008.

Please submit *all* of the application materials described below.

The following forms and documents are required to be submitted under this announcement:

1. Application for Federal Assistance (SF-424)
2. Budget Information for Non-Construction Programs (SF-424A)
3. Key Contact List
4. Project Narrative and Supporting Documentation

Documents 1 through 4 listed under Application Materials in Section IV.A of this announcement should appear in the "Mandatory Documents" box on the grants.gov Grant Application Package page.

For documents 1-3, click on the appropriate form and then click "Open Form" below the box. The fields that must be completed will be highlighted in yellow. Optional fields and completed fields will be displayed in white. If you enter an invalid response or incomplete information in a field, you will receive an error message. When you have finished filling out each form, click "Save". When you return to the electronic Grant Application Package page, click on the form you just completed, and then click on the box that says, "Move Form to Submission List". This action will move the document over to the box that says, "Mandatory Completed Documents for Submission."

For document 4, you will need to attach electronic files. Prepare each of the documents as described above in items 4.a through 4.e of Section IV.A and save the documents to your computer as an MS Word, PDF or WordPerfect file. When you are ready to attach your proposal to the application package, click on "Project Narrative Attachment Form", and open the form. Click "Add Mandatory Project Narrative File", and then attach your proposal (previously saved to your computer) using the browse window that appears. You may then click "View Mandatory Project Narrative File" to view it. Enter a brief descriptive title of your project in the space beside "Mandatory Project Narrative File Filename", the filename should be no more than 40 characters long. If there are other attachments that you would like to submit to accompany your proposal, you may click "Add Optional Project Narrative File" and proceed as before. When you have finished attaching the necessary documents, click "Close Form". When you return to the "Grant Application Package" page, select "Project Narrative Attachment Form" and click "Move Form to Submission List". The form should now appear in the box that says, "Mandatory Completed Documents for Submission".

Once you have finished filling out all of the forms/attachments and they appear in one of the "Completed Documents for Submission" boxes, click the "Save" button that appears at the top of the Web page. It is suggested that you save the document a second time, using a different name, since this will make it easier to submit an amended package later if necessary. Please use the following format when saving your file: "Applicant Name – FY 08 (grant category; e.g., Assoc Prog Supp) – 1st Submission" or "Applicant Name – FY 08 (grant category) – Back-up Submission." If it becomes necessary to submit an amended package at a later date, then the name of the 2nd submission should be changed to "Applicant Name – FY 08 (grant category) – 2nd Submission."

Once your application package has been completed and saved, send it to your AOR for submission to the U.S. EPA through Grants.gov. Please advise your AOR to close all other software programs before attempting to submit the application package through Grants.gov.

In the "Application Filing Name" box, your AOR should enter your organization's name (abbreviate where possible), the fiscal year (e.g., FY08), and the grant category (e.g., Assoc Prog Supp). The filing name should not exceed 40 characters. From the "Grant Application Package" page, your AOR may submit the application package by clicking the "Submit" button that appears at the top of the page. The AOR will then be asked to verify the agency and funding opportunity number for which the application package is being submitted. If problems are encountered during the submission process, the AOR should reboot his/her computer before trying to submit the application package again. [It may be necessary to turn off the computer (not just restart it) before attempting to

submit the package again.] If the AOR continues to experience submission problems, he/she should contact grants.gov for assistance (Phone: 1-800-518-4726, Email: http://www.grants.gov/help/help.jsp). If submission problems are not quickly resolved, contact the NERL electronic submission support person, Walt Stutts at 513/569-7487 or stutts.walter@epa.gov.

Application packages submitted through grants.gov will be time/date stamped electronically.

If you have not received a confirmation of receipt from EPA (not from grants.gov) within 30 days of the application deadline, please contact the individual identified in Section VII. Failure to do so may result in your application not being reviewed.

C. Submission Instructions for Printed Hard-Copy Applications

Submit a complete application including all of the documents identified in Section IV.A of this announcement. The complete application *must be* sent through regular mail, express mail, or a major courier to: **Raina Porras, U.S. EPA, 944 E. Harmon Avenue, Las Vegas, NV 89119**

Because of security concerns, applications cannot be personally delivered. To be considered timely, printed applications must be received by 2:00 p.m. local time in Las Vegas, NV on July 15, 2008 from the U.S. Postal Service or a major courier. Applications received after the deadline will not be considered and will be returned to the submitter. Printed hard-copy applications, including all documents stated in Section IV.A. above, must be submitted in the original with 3 copies and should be double-sided. Grant application forms can be found at http://www.epa.gov/ogd/AppKit/application.htm

D. Intergovernmental Review

Executive Order 12372, "Intergovernmental Review of Federal Programs," applies to most EPA programs and assistance agreements, unless the program or assistance agreement supports tribal, training/fellowships (other than Wastewater and Small Water Systems Operator training programs), and research and development (with some exceptions). The SF424 refers to this Executive Order Requirement. National research programs are generally exempt from review unless the proposals (a) require an Environmental Impact Statement (EIS), or (b) do not require an EIS but will be newly initiated at a particular site and require unusual measures to limit the possibility of adverse exposure or hazard to the general public, or (c) have a unique geographic focus and are directly relevant to the governmental responsibilities of a State or local government within that geographic area. To determine whether their state participates in this process, and how to comply, applicants should consult: http://www.whitehouse.gov/omb/grants/spoc.html.

E. Funding Restrictions

The EPA anticipates fully funding this project at $2,500,000 upon award of the agreement.

F. Partnerships

EPA awards funds to one eligible applicant as the "recipient" even if other eligible applicants are named as "partners" or "co-applicants" or members of a "coalition" or "consortium". The recipient is accountable to EPA for the proper expenditure of funds.

Funding may be used to provide subgrants or subawards of financial assistance to fund partnerships provided the recipient complies with applicable requirements for subawards or subgrants including those contained in 40 CFR Parts 30 or 31, as appropriate. Successful applicants must compete contracts for services and products and conduct cost and price analyses to the extent required by the procurement provisions of these regulations. The regulations also contain limitations on consultant compensation. Applicants are not required to identify contractors or consultants in their proposal. While applicants are not required to identify contractors or consultants in their proposal, if they do so the fact that an applicant selected for award has named a specific contractor or consultant in the proposal EPA selects does not relieve the applicant of its obligations to comply with competitive procurement requirements. Please note that applicants may not award sole source contracts to consulting, engineering or other firms assisting applicants with the proposal based solely on the firm's role in preparing the proposal.

Successful applicants cannot use subgrants or subawards to avoid requirements in EPA grant regulations for competitive procurement by using these instruments to acquire commercial services or products from for-profit organizations to carry out its assistance agreement. The nature of the transaction between the recipient and the subawardee and subgrantee must be consistent with the standards for distinguishing between vendor transactions and subrecipient assistance under Subpart B Section .210 of OMB Circular A-133, and the definitions of "subaward" at 40 CFR 30.2(ff) or "subgrant" at 40 CFR 31.3, as applicable. EPA will not be a party to these transactions.

Section V of the announcement describes the evaluation criteria and evaluation process that will be used by EPA to make selections under this announcement. During this evaluation, except for those criteria that relate solely to the applicant's qualifications, past performance, and reporting history, the review panel will consider (to the extent applicable under any relevant criteria) the qualifications, expertise, and experience of

i) an applicant's named subawardees/subgrantees identified in the proposal/application if the applicant demonstrates in the proposal/application that if it receives an award that the subaward/subgrant will be properly awarded consistent with the applicable regulations in 40 CFR Parts 30 or 31. For example, applicants must not use subawards/subgrants to obtain commercial services or products from for profit firms or individual consultants.

(ii) an applicant's named contractor(s), including consultants, identified in the proposal/application if the applicant demonstrates in its proposal/application that the contractor(s) was selected in compliance with the competitive Procurement Standards in 40 CFR Part 30 or 40 CFR 31.36 as appropriate. For example, an applicant must demonstrate that it selected the contractor(s) competitively or that a proper non-competitive sole-source award consistent with the regulations will be made to the contractor(s), that efforts were made to provide small and disadvantaged businesses with opportunities to compete, and that some form of cost or price

analysis was conducted. EPA may not accept sole source justifications for contracts for services or products that are otherwise readily available in the commercial marketplace.

EPA will not consider the qualifications, experience, and expertise of proposed subawardees/subgrantees and/or contractors during the proposal/application evaluation process unless the applicant complies with these requirements.

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G. Amendments

Amendments will be posted on grants.gov under this Funding Opportunity Number and the due date for applications will be extended if deemed appropriate.

H. Confidentiality

By submitting an application in response to this solicitation, the applicant grants the EPA permission to make limited disclosures of the application to technical reviewers both within and outside the Agency for the express purpose of assisting the Agency with evaluating the application. Information from a pending or unsuccessful application will be kept confidential to the fullest extent allowed under law; information from a successful application may be publicly disclosed to the extent permitted by law.

In accordance with 40 CFR 2.203, applicants may claim all or a portion of the application/proposal as confidential business information (for example, hypotheses or methodologies contained in the research narrative that the applicant wishes to protect from possible public disclosure). EPA will evaluate confidentiality claims in accordance with 40 CFR Part 2. Applicants must clearly mark applications/proposals or portions of applications/proposals they claim as confidential. If no claim of confidentiality is made, the EPA is not required to make an inquiry to the applicant otherwise required by 40 CFR 2.204(c)(2) prior to disclosure.

I. Pre-proposal/Application Assistance and Communications.

In accordance with EPA's Assistance Agreement Competition Policy (EPA Order 5700.5A1), EPA staff will not meet with individual applicants to discuss draft proposals, provide informal comments on draft proposals, or provide advice to applicants on how to respond to ranking criteria. Applicants are responsible for the contents of their applications/proposals. However, consistent with the provisions in the announcement, EPA will respond to questions from individual applicants regarding threshold eligibility criteria, administrative issues related to the submission of the proposal, and requests for clarification about the announcement.

J. Management Fees

Management Fees: When formulating budgets for proposals/applications, applicants must not include management fees or similar charges in excess of the direct costs and indirect costs at the rate approved by the applicant’s cognizant audit agency, or at the rate provided for by the terms of the

agreement negotiated with EPA. The term "management fees or similar charges" refers to expenses added to the direct costs in order to accumulate and reserve funds for ongoing business expenses, unforeseen liabilities, or for other similar costs that are not allowable under EPA assistance agreements. Management fees or similar charges may not be used to improve or expand the project funded under this agreement, except to the extent authorized as a direct cost of carrying out the scope of work.

V. Application Review Information

Each application that meets the eligibility requirements set forth in Section III will be subjected to technical and programmatic reviews. The technical review will be conducted by a panel consisting of at least two non-EPA reviewers and one EPA reviewer who are able to demonstrate expertise and a lack of any conflict of interest. The purpose is to evaluate the scientific merit of the proposal and the capability of the applicant to complete the project as proposed. The programmatic review will be conducted by other qualified EPA personnel who are able to demonstrate a lack of any conflict of interest. The purpose is to evaluate the applicant's past performance in conducting projects of similar size, scope and relevance.

The following criteria will be used in the evaluation process:

Technical Evaluation Criteria

1. Adequacy of the Technical Approach –
   a. The overall scientific merit of the technical approach for achieving the goals stated under the Funding Priorities/Focus in Section I. (50%)

      (1) Background, need, and hypotheses: The applicant demonstrates a clear understanding of the scientific issues and goals of the research. The proposed hypotheses are sound and address the issues and can be anticipated to lead to a substantial improvement in the understanding of the determinants of exposure for the six early lifestage age groups for children under three years of age. (5%)
      (2) The applicant's general technical, statistical, and methodological approaches for conducting the proposed study are appropriate and adequate to test the proposed hypotheses, are scientifically sound, and have a high likelihood of success. (7%)
      (3) The applicant understands issues associated with observational studies involving young children and demonstrates that the proposed approach clearly addresses the complex scientific and ethical issues associated with observational human exposure measurement studies including, but not limited to, recruitment, retention, use of compensation (both monetary and non-monetary), communication between community/participants/researchers/media, intervention, and education. (7%)
      (4) The proposed approach describes and demonstrates how biomarkers will be used in the study to test the hypotheses and/or evaluate results of the tests of the hypotheses. (7%)
      (5) The proposal demonstrates that innovative approaches will be used in the design and

implementation of the study, community interactions, incorporating exposure mitigation strategies, and maximizing benefits to the community and participants in the study. (7%)

(6) The applicant has identified a community in which to perform an observational study that will adequately test the hypotheses. The applicant has identified community groups and community representatives to facilitate a community-based research study in the community and provides documentation to support the planned collaboration with the community. (4%)

(7) The applicant demonstrates an appropriate and adequate approach and plan for engaging community groups and their representatives in an observational study and for maintaining community engagement throughout a study. (3%)

(8) The applicant demonstrates that the proposed study cohort will be suitable for testing the hypotheses. (7%)

(9) The applicant clearly demonstrates capabilities and experience conducting community-based research. (3%)

b. The plan for tracking and measuring progress toward achieving the expected environmental outputs and outcomes. (5%)

2. Qualifications of the proposed key personnel and adequacy of time commitment. (20%)

3. Institutional capability including laboratory space and equipment that will be available to complete the project. (10%)

4. Quality Management Plan that describes the organization's quality system. (5%)

5. Programmatic Evaluation Criterion. (10%)

The applicant's demonstration of the programmatic capability to successfully carry out the proposed project taking into account such factors as its: (i) past performance of the proposed Lead Principal Investigator in successfully completing federally or non-federally funded assistance agreements of similar size, scope and relevance to the proposed project during the past five years, (ii) history of meeting reporting requirements on prior or current assistance agreements (during the past five years) with federal and/or non-federal organizations and submitting acceptable final technical reports, and (iii) past performance in documenting and/or reporting on its progress towards achieving the expected outcomes and outputs (e.g., results) under prior or current assistance agreements (during the past five years) with federal and/or non-federal organizations (and if such progress was not made whether the documentation and/or reports satisfactorily explained why not).

Organizations that have no relevant or available past performance and/or reporting information will be given a neutral rating for those criteria. In evaluating applicants under this criterion the Agency may consider information from other sources including agency files and prior/current grantors (e.g., to verify and/or supplement the information provided by the applicant).

Other Factors: When two or more of the highly rated proposals receive equivalent rankings, the

respective budgets will be evaluated by EPA staff for cost reasonableness and cost realism in order to determine which applicant will receive the award. The proposal that is determined to be the most reasonable/realistic will be selected for award. The amount of cost sharing proposed (if any) will not result in additional points for any applicant, but will be considered in the evaluation of the reasonableness and realism of the overall budget.

Review and Selection Process:

Evaluation Review Process: The eligibility review discussed in Section III will be conducted by EPA personnel who are not part of the technical review panel. The technical review panel, which reviews the technical proposal for scientific merit and organizational capabilities, shall consist of at least one internal EPA reviewer and at least two non-EPA reviewers who are able to demonstrate technical expertise and a lack of any conflict of interest. The technical review panel will review the proposal against the criteria above identified as Technical Evaluation Criteria and rank the proposal based upon this evaluation. The programmatic review will be conducted by one or more EPA reviewers who are not part of the technical evaluation panel and who are able to demonstrate a lack of any conflict of interest. The programmatic reviewer(s) will review the proposal against the criteria identified as Programmatic Evaluation Criteria above and rank the proposals based upon this evaluation. The results of the Technical and Programmatic Evaluations will be combined to determine the overall ranking of each evaluated applicant.

Source Selection: EPA will make a selection of the applicant for award based upon the combined rankings of the technical and programmatic reviews and the other factors discussed above. EPA may negotiate changes to the proposal with the selected applicant so long as they do not affect the integrity of the competition. For example, EPA will discuss significant comments received from the technical reviewers, aspects of the budget that may be questionable, the proposed terms and conditions for the agreement, and the nature and extent of EPA collaboration. The Decision Official is an Office of Research and Development (ORD) manager who will determine which applicant should receive the award.

Following EPA's determination of awardee(s), all applicants will be notified regarding their status. Final applications will be requested from those eligible entities whose proposal has been successfully evaluated and preliminarily recommended for award. Those entities will be provided with instructions and a due date for submittal of the final application package.

Rejection Factors: Applications may be rejected because they fail to comply with the administrative requirements of the RFA, they are found to lack relevancy, they are judged technically and/or programmatically unacceptable, or they are not deemed suitable for award due to other factors (if identified). EPA reserves the right to reject all proposals or applications and make no awards.

Anticipated Announcement and Award Dates: The anticipated award date is December 1, 2008.

VI. Award Administration Information

Award Notices: Notice of award will be made in writing by an official in the EPA Grants and Interagency Agreement Management Division. Preliminary selection by the Decision Official in the Office of Research and Development does not guarantee an award will be made. Applicants are cautioned that only a grants officer can bind the Government to the expenditure of funds. No commitment on the part of EPA should be inferred from technical or budgetary discussions with an EPA Program Official. A Principal Investigator or organization that makes financial or personnel commitments in the absence of a grant or cooperative agreement signed by the EPA Grants Award Official does so at their own risk.

Disputes: Assistance agreement competition-related disputes will be resolved in accordance with the dispute resolution procedures published in 70 FR (Federal Register) 3629, 3630 (January 26, 2005) which can be found at http://www.epa.gov/ogd/competition/resolution.htm. Copies of these procedures may also be requested by contacting the Agency Contact identified in Section VII.

Administrative and National Policy Requirements:

Regulations and OMB Coverage:

Grants and agreements with institutions of higher education, hospitals, and other non-profit organizations are subject to 40 CFR Parts 30 and 40 and OMB Circular A-122 for non-profits and A-21 for institutions of higher learning.

Grants and agreements with state, local, and tribal governments are subject to 40 CFR Parts 31 and 40 and OMB Circular A-87.

Programmatic Terms and Conditions: Terms and conditions will be negotiated with the selected recipient covering the following requirements:

- An acceptable study design document (to be completed in 2009) describing the observational study to be performed that adequately addresses issues identified in the planned EPA document on scientific and ethical approaches for observational exposure studies.

- An acceptable quality assurance document, i.e., Quality Assurance Project Plan (QAPP), shall be due within 45 calendar days of completion of the final study design.

- Approval of the protocol for protection of human subjects by an Institutional Review Board prior to the start of data collection.

- To further the assistance-agreement objectives of public support and stimulation, applicants must agree to make methods, models, and data resulting from this agreement accessible to the public and to EPA researchers.

- The nature and extent of collaboration between EPA and the recipient.

- OBM clearance shall be obtained prior to the collection of identical information from 10 or more non-Federal respondents.

Reporting:

Quarterly Progress Reports: The selected recipient will be required to submit quarterly progress reports summarizing technical progress, difficulties encountered, and planned activities for the next quarter. Each report shall include a summary of expenditures.

Final Report: The selected recipient will be required to submit a final report within 90 calendar days of the completion of the period of performance.

Nonprofit Administrative Capability Clause

Non-profit applicants that are recommended for funding under this announcement are subject to pre-award administrative capability reviews consistent with Section 8b, 8c and 9d of EPA Order 5700.8 - Policy on Assessing Capabilities of Non-Profit Applicants for Managing Assistance Awards (http://www.epa.gov/ogd/grants/award/5700_8.pdf). In addition, non-profit applicants that qualify for funding may, depending on the size of the award, be required to fill out and submit to the Grants Management Office the Administrative Capabilities Form with supporting documents contained in Appendix A of EPA Order 5700.8.

VII. Agency Contact

The primary agency contact for this RFA is **Raina Porras** at:
U. S. EPA, 944 E. Harmon Avenue, Las Vegas, NV 89119
Telephone: (702) 798-2274
E-mail: Porras.Raina@epa.gov (applications may not be submitted via email)

If unable to reach Raina Porras, contact Mr. Walter Stutts at:
Telephone: (513) 569-7487
E-mail: stutts.walter@epa.gov

VIII. Other Information

Questions: Questions should be submitted in writing by June 30, 2008. Do not attempt to seek information regarding this RFA from any source other than those identified in Section VII as the information provided may be erroneous. Questions that are considered significant will be answered via an amendment to this RFA.

Animal and Human Subject Research:

a. Human Subjects: A grant applicant must agree to meet all EPA requirements for studies using

human subjects prior to implementing any work with these subjects. These requirements are given in 40 C.F.R. § 26. For observational studies involving children, pregnant women, or nursing mothers please refer to Subparts B & D of 40 C.F.R. § 26. U.S. Department of Health and Human Services regulations at 45 C.F.R. § 46.101 (e) have long required "...compliance with pertinent Federal laws or regulations which provide additional protection for human subjects." EPA's regulation at 40 C.F.R. Part 26 is such a pertinent Federal regulation. Therefore, the applicant's Institutional Review Board (IRB) approval must state that the applicant's study meets the EPA's regulations at 40 C.F.R. § 26. No work involving human subjects, including recruiting, may be initiated before the EPA has received a copy of the applicant's IRB approval of the project and the EPA has also provided approval. Where human subjects are involved in the research, the recipient must provide evidence of subsequent IRB reviews, including amendments or minor changes of protocol, as part of annual reports.

b. Animal Welfare: A grant recipient must agree to comply with the Animal Welfare Act of 1966 (P.L. 89-544), as amended, 7 U.S.C. 2131-2156. The recipient must also agree to abide by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training." (50 Federal Register 20864-20865 (May 20,1985))

This clause applies if a research facility (defined as any school (except elementary or secondary), institution, organization or person) receives funds under a grant from a federal agency for the purpose of carrying out research, tests, or experiments involving animals.

Data Access and Information Release: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. If such data are requested by the public, the EPA must ask for it, and the grantee must submit it, in accordance with A-110 and EPA regulations at 40 C.F.R. 30.36.

DUNS Number: Grant applicants are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. OMB has determined that there is a need for improved statistical reporting of Federal grants and cooperative agreements. Use of the DUNS number government-wide will provide a means to identify entities receiving those awards and their business relationships. The identifier will be used for tracking purposes, and to validate address and point of contact information.

A DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (Grants.gov). The DUNS number will supplement other identifiers required by statute or regulation, such as tax identification numbers. Organizations can receive a DUNS number in one day, at no cost, by calling the dedicated toll-free DUNS Number request line at 1−866−705−5711. Individuals who would personally receive a grant or cooperative agreement award from the Federal government apart from any business or non-profit organization they may operate are exempt from this requirement. The website where an organization can obtain a DUNS number is: http://www.dnb.com. This takes 30 business days and there is no cost unless the organization requests expedited (1-day) processing, which includes a fee of $40.